IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Kunzler et al.	: Confirmation No.: 1847 :
Serial No. : 10/801,741 Filed: March 16, 2004	: Examiner: : Group Art Unit: 1621
Title: VITREORETINAL SILICONE TAMPONADES MADE BY SUPERCRITICAL FLUID EXTRACTION	: Atty. Dkt. No.: P03074D1 :

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DECLARATION OF DHARMENDRA JANI UNDER 37 C.F.R. § 1.132

I am a coinventor of the invention described in this application. The invention is directed to a method of using a purified silicon oil as a vitreous substitute (tamponade) in an ophthalmic surgical procedure. The purified silicon oil is obtained by using a supercritical fluid containing carbon dioxide as an extraction fluid to remove low molecular weight cyclics and oligomers from crude preparations of the oil.

Ocular tamponades are vitreous substitutes that are used to reposition the retina of an eye in instances where a reattachment is not achievable by natural healing or by laser coagulation. The purpose of a vitreous substitute is to provide a long-term pressurizing fluid to position and maintain the retina in place during the natural healing process. Present commercial tamponades include perfluorocarbon-liquids, balanced salt solutions and silicone oil. Silicone oil is typically the tamponade of choice in cases of severe retina detachment, that is, if the tamponade must remain in the eye for periods of two months or longer.

Silicone oil or fluid is prepared by a ring-opening polymerization of strained cyclic silicones. The crude reaction product includes the desired high molecular weight silicone fluid as well as low molecular weight cyclic siloxanes and oligomers. These low molecular weight compounds are believed to be responsible for the undesirable emulsification phenomenon that is sometimes observed with silicone fluid tamponades. Traditionally, the method of purifying silicone oil involves the use of a lengthy and difficult solvent extraction process whereby the crude silicone oil is slowly added to an extraction solvent such as acetone. The low molecular weight compounds are soluble in the extraction solvent and can be removed by a phase separation of the oil and solvent. Multiple extraction cycles are required to provide the desired purity level of the silicon oil. The process is lengthy (can take four to six weeks) and produces significant amounts of waste extraction solvent.

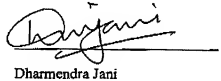
We investigated the use of a supercritical extraction process to obtain a purified silicon fluid for ophthalmic applications. The process not only proved to be more efficient (e.g., less time, less waste solvent) than solvent extraction, but also, provided a silicon fluid with unexpected and highly desirable interfacial tension characteristics. Interfacial stability is very important for a long-term ocular tamponade because the tamponade will eventually come in contact with the aqueous humour of the eye. In such an instance, any interfacial mixing can result in emulsification or clouding of the vitreous substitute over time. As one can imagine, clouding of the vitreous substitute results in vision loss.

As indicated on Chart 1 on page 11 of the application, the interfacial tension of crude silicon oil and even that of a silicon fluid obtained by solvent extraction could not be measured because of the interfacial mixing or interfacial instability of the oil and aqueous phases.

In contrast, the discrete oil/water phases (high interfacial stability) observed with the silicon fluid purified by supercritical extraction is a very important property for an ocular tamponade for the reasons stated above. This

high interfacial stability was unexpected and provides a silicon fluid ideally suited for ophthalmic applications.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements can jeopardize the validity of the application or any patent issuing thereon.



Dharmendra Jani